IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV, *Plaintiffs*, v. MYLAN LABORATORIES LIMITED, *Defendants*.	Civil Action No. 2:19-cv-16484 (CCC) (MF)

JOINT STIPULATION AND ORDER REGARDING
UNDISPUTED CLAIM LIMITATIONS OF U.S. PATENT NO. 9,439,906

Plaintiffs Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (collectively, "Janssen") and Defendant Mylan Laboratories Limited ("Mylan") (together with Janssen, "the parties") respectfully submit this Joint Stipulation and Proposed Order Regarding Undisputed Claim Limitations of U.S. Patent No. 9,439,906 ("the '906 Patent"):

WHEREAS, Mylan filed Abbreviated New Drug Application No. 213124 (the "ANDA") for generic versions of Invega Sustenna® ("Mylan's Proposed Generic Products");

WHEREAS, the ANDA contains a "Paragraph IV Certification" to the '906 Patent, asserting that the '906 Patent is invalid and/or not infringed;

WHEREAS, Janssen has sued Mylan for infringement of claims 1-21 ("Asserted Claims") the '906 Patent under 35 U.S.C. § 271;

NOW THEREFORE, IT IS HEREBY STIPULATED, AGREED AND ORDERED that:

1. Mylan admits that Mylan's Proposed Generic Products meet the following claim limitations ("the Undisputed Claim Limitations"):

a. that "the formulation is an aqueous nanoparticle suspension comprises (a) from 3 to 20% (w/v) of the paliperidone palmitate having an average particle size (d50) of from about 1600 nm to about 900 nm; (b) from 0.5 to 3% (w/v) of a wetting agent wherein the wetting agent is polysorbate 20; (c) one or more buffering agents sufficient to render the composition neutral to very slightly basic (pH 8.5); (d) from 0.5 to 3% (w/v) of a suspending agent wherein the suspending agent is polyethylene glycol 4000; and (e) up to 2% (w/v) preservatives; and (f) water q.s. ad 100%" as recited in claim 17 of the '906 Patent,

b. that "the concentration of paliperidone palmitate is 156 mg/ml in the aqueous nanoparticle suspension" as recited in claim 18 of the '906 Patent,

c. that "the sustained release depot formulation is an aqueous nanoparticle suspension consists essentially of (a) 156 mg/ml of the paliperidone palmitate having an average particle size (d50) of from about 1600 nm to about 900 nm; (b) 12 mg/ml of polysorbate 20; (c) one or more buffering agents sufficient to render the composition neutral to very slightly basic (pH 8.5); (d) 30 mg/ml of a suspending agent wherein the suspending agent is polyethylene glycol 4000; and (f) water q.s. ad 100%" as recited in claim 19 of the '906 Patent,

d. that "in the buffering agents contained in the aqueous nanoparticle suspension are citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide" as recited in claim 20 of the '906 Patent, and

e. that "the aqueous nanoparticle suspension is in the range of pH 7 to 7.5" as recited in claim 21 of the '906 Patent.

2. Janssen will not pursue requests for production of (i) samples of Mylan's Proposed Generic Products or (ii) samples from the laboratory, exhibit, registration, or pilot-scale batches that Mylan prepared in connection with its ANDA.

3. This Stipulation does not limit Mylan's rights (i) to assert non-infringement of the Asserted Claims on any basis other than the Undisputed Claim Limitations, or (ii) to contest the validity of the Asserted Claims.

4. This Stipulation does not limit Janssen's rights to seek discovery other than that described in paragraph 2.

Dated: August 5, 2020

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IT IS SO ORDERED this 7 day of August __, 2020.

Hon. Claire C. Cecchi, U.S.D.J.